

American Society of Testing and Materials International (ASTM)

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Chair - F04.42 Biomaterials and
Biomolecules

Past Vice-Chair of Main
Committee F04

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ASTM

- Voluntary standards developing organization
 - Divided into 143 topic-specific Technical Committees
 - Technical Committee F04 on Medical and Surgical Materials and Devices, subcommittee F04.04 Div. IV TEMPS
- Mission statement
 - To be recognized globally as the premier developer and provider of voluntary consensus standards, related technical information, and services that promote public health and safety, support the protection and sustainability of the environment, and the overall quality of life;
 - contribute to the reliability of materials, products, systems and services; and facilitate international, regional, and national commerce.
- 12,000 ASTM standards (280 from F04) developed by consensus and collaboration.

ASTM

- History

- ASTM formed in 1898, F04 in 1962 and F04.04 on 09/07/1995.

- Membership/Leadership

- 900+ members in F04, >30,000 members overall in ASTM
 - F04 Global participation: 31 Countries, ASTM overall -150

- Funding

- ASTM is a not-for-profit organization
 - supported primarily by sales of standards

- Education/Training

- symposia, workshops and publications

- F04 Meetings: twice/year (May + November)

- Partnerships

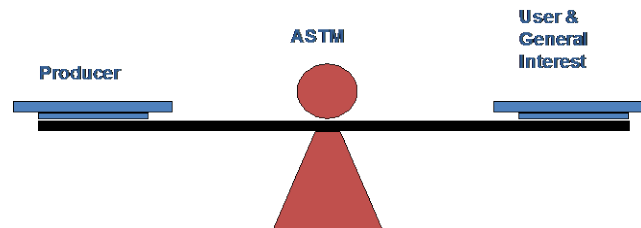
- Stakeholders: producers, users, general interest, other standard organizations

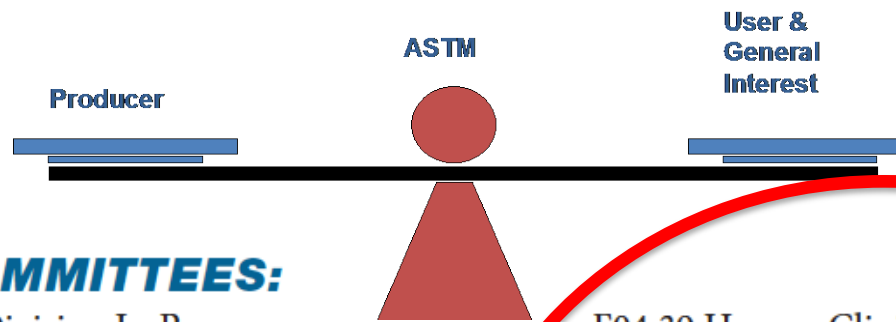
ASTM fosters global access to transparent standards development

- Memorandum of Understanding – MOU program.
 - Initiated in 2001.
 - promotes communication between ASTM International and national standards bodies worldwide
 - facilitates the development of national standards that will aid each country's health, safety, environmental, and economic conditions.
 - technical experts from any of the countries where MOUs have been signed can participate freely as full voting members in the ASTM standards development process

ASTM Standard Development

- Types of standards
 - Guide, practice, terminology, standard
- Standards written by task force within a subcommittee. Initiation of a work item.
- Draft reviewed and revised by task force until ready for ballot at subcommittee level. A negative vote keeps the ballot at subcommittee level for additional revisions. Final ballot at committee level: F04.
- Balloting process ensures fairness and balanced participation.
- Leads to high quality, market relevant standards.





F04 **SUBCOMMITTEES:**

- F04.01 Division I - Resources
 - F04.11 Polymeric Materials
 - F04.12 Metallurgical Materials
 - ✓ • F04.13 Ceramic Materials
 - F04.15 Material Test Methods
 - F04.15.11 MR Standards
 - F04.16 Biocompatibility Test Methods
 - F04.18 Device Retrieval Analysis
 - F04.02 Division II - Orthopaedic Devices
 - F04.21 Osteosynthesis
 - F04.22 Arthroplasty
 - F04.25 Spinal Devices
 - F04.03 Division III - Medical/Surgical Devices
 - F04.30 Cardiovascular Standards
 - F04.31 Neurosurgical Standards
 - F04.32 Plastic and Reconstructive Surgery
 - F04.33 Medical/Surgical Instruments
 - F04.34 Urological Materials and Devices
 - F04.35 GI Applications
 - F04.37 Implantable Hearing Devices (IHDs)
 - F04.38 Computer Assisted Orthopaedic Surgical Systems
 - F04.39 Human Clinical Trials
 - F04.04 Division IV - Tissue Engineered Medical Products
 - F04.41 Classification and Terminology for TEMPs
 - ✓ • F04.42 Biomaterials and Biomolecules for TEMPs
 - ✓ • F04.43 Cells and Tissue Engineered Constructs for TEMPs
 - F04.44 Assessment for TEMPs
 - F04.45 Adventitious Agents Safety
 - F04.46 Cell Signaling
 - F04.05 Computer Assisted Orthopaedic Surgical Systems
 - F04.90 Executive
 - F04.91 Awards
 - F04.92 Planning
 - F04.93 US TAG ISO/TC 150 - Implants for Surgery
 - F04.94 Finance
 - F04.95 US TAG ISO/TC 168 - Prosthetics and Orthotics
 - F04.97 Editorial and Terminology
- ✓ = standards I've been task force chair of

F04 Standards Topics

- Medical devices: orthopaedic, cardiovascular, plastic and reconstructive surgery, urological, etc.
- Test methods and specifications for tissue engineering/regenerative medicine
- Biomaterials
- Biomolecules
- Cells
- Tissues – natural and synthetic

Current standards and work items -

F04.41 ASTM subcommittee

- **ASTM Subcommittee F04.41 on Classification and Terminology for TEMPs (3)**
- [F2311-08 Standard Guide for Classification of Therapeutic Skin Substitutes](#)
- [F2312-11 Standard Terminology Relating to Tissue Engineered Medical Products](#)
- ★• [WK43184](#) New Specification for Classification of Cellular and/or Tissue-Based Products (CTPs) for Wounds

★ = Specific test method

ASTM – Current standards and work items - F04.42

• Subcommittee F04.42 on Biomaterials and Biomolecules for TEMPs (20)



[F2027-08 Standard Guide for Characterization and Testing of Raw or Starting Biomaterials for Tissue-Engineered Medical Products](#)

- [F2064-00\(2006\)e1 Standard Guide for Characterization and Testing of Alginates as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Products Application](#)
- [F2103-11 Standard Guide for Characterization and Testing of Chitosan Salts as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Product Applications](#)



[F2131-02\(2012\) Standard Test Method for In Vitro Biological Activity of Recombinant Human Bone Morphogenetic Protein-2 \(rhBMP-2\) Using the W-20 Mouse Stromal Cell Line](#)

- [F2150-07 Standard Guide for Characterization and Testing of Biomaterial Scaffolds Used in Tissue-Engineered Medical Products](#)
- [F2212-11 Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products \(TEMPs\)](#)



[F2259-10\(2012\)e1 Standard Test Method for Determining the Chemical Composition and Sequence in Alginate by Proton Nuclear Magnetic Resonance \(¹H NMR\) Spectroscopy](#)



[F2260-03\(2012\)e1 Standard Test Method for Determining Degree of Deacetylation in Chitosan Salts by Proton Nuclear Magnetic Resonance \(¹H NMR\) Spectroscopy](#)

- [F2347-11 Standard Guide for Characterization and Testing of Hyaluronan as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications](#)
- [F2450-10 Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue Engineered Medical Products](#)



[F2602-08e1 Standard Test Method for Determining the Molar Mass of Chitosan and Chitosan Salts by Size Exclusion Chromatography with Multi-angle Light Scattering Detection \(SEC-MALS\)](#)

- [F2603-06\(2012\) Standard Guide for Interpreting Images of Polymeric Tissue Scaffolds](#)
- [F2605-08e1 Standard Test Method for Determining the Molar Mass of Sodium Alginate by Size Exclusion Chromatography with Multi-angle Light Scattering Detection \(SEC-MALS\)](#)



[F2791-09 Standard Guide for Assessment of Surface Texture of Non-Porous Biomaterials in Two Dimensions](#)

- [F2883-11 Standard Guide for Characterization of Ceramic and Mineral Based Scaffolds used for Tissue-Engineered Medical Products \(TEMPs\) and as Device for Surgical Implant Applications](#)

- [F2900-11 Standard Guide for Characterization of Hydrogels used in Regenerative Medicine](#)

- [WK24374](#) New Guide for determining Darcy permeability coefficients for porous tissue scaffolds.

- [WK39698](#) New Test Method: Using NIST Tissue Engineering Reference Scaffolds for Cell Culture Tests



[WK37592](#) New Guide for In vitro release of biomolecules from matrices for TEMPs



[WK43011](#) New Specification for Characterization and Standardization of Polymerizable Collagen-Based Products and Associated Collagen-Cell Interactions



= Specific test method



= standards I've been task force chair of

ASTM – Current standards and work items **F04.43**

- **Subcommittee F04.43 on Cells and Tissue Engineered Constructs for TEMPs (9)**

- ★ [F2149-01\(2007\) Standard Test Method for Automated Analyses of Cells-the Electrical Sensing Zone Method of Enumerating and Sizing Single Cell Suspensions](#)
- [F2210-02\(2010\) Standard Guide for Processing Cells, Tissues, and Organs for Use in Tissue Engineered Medical Products](#)
- [F2315-11 Standard Guide for Immobilization or Encapsulation of Living Cells or Tissue in Alginate Gels](#)
- [F2664-11 Standard Guide for Assessing the Attachment of Cells to Biomaterial Surfaces by Physical Methods](#)
- [F2739-08 Standard Guide for Quantitating Cell Viability Within Biomaterial Scaffolds](#)
- ★ [F2944-12 Standard Test Method for Automated Colony Forming Unit \(CFU\) Assays—Image Acquisition and Analysis Method for Enumerating and Characterizing Cells and Colonies in Culture](#)
- ✓ • [WK28890](#) New Guide for in vitro Osteoblast Differentiation Assays
- ★ [WK36232](#) New Test Method for Use of a Centrifugation Method to Quantify/Study Cell-Material Adhesive Interactions
- ✓★ [WK37594](#) New Practice for Quantification of calcium deposits in osteogenic culture of progenitor cells using fluorescent image analysis

★ = Specific test method

✓ = standards I've been task force chair of

ASTM – Current standards and work items of **F04.44 subcommittee**

- **Subcommittee F04.44 on Assessment for TEMPs**
- [F2451-05\(2010\) Standard Guide for *in vivo* Assessment of Implantable Devices Intended to Repair or Regenerate Articular Cartilage](#)
- [F2529-13 Standard Guide for *in vivo* Evaluation of Osteoinductive Potential for Materials Containing Demineralized Bone \(DBM\)](#)
- [F2721-09 Standard Guide for Pre-clinical *in vivo* Evaluation in Critical Size Segmental Bone Defects](#)
- [F2884-12 Standard Guide for Pre-clinical *in vivo* Evaluation of Spinal Fusion](#)
- [F2903-11 Standard Guide for Tissue Engineered Medical Products \(TEMPS\) for Reinforcement of Tendon and Ligament Surgical Repair](#)
- [WK16591](#) New Guide for Guide for the In Vivo Assessment of Bone Inductive Materials
- [WK28852](#) New Guide for Pre-clinical *in vivo* evaluation in critical size metaphyseal bone defects
- [WK21657](#) New Guide for Characterization and Assessment of Vascular Graft Tissue-Engineered Medical Products (TEMPS)
- [WK26326](#) New Guide for Characterization and Assessment of Heart Valve Tissue Engineered Medical Products
- [WK28783](#) New Guide for Pre-clinical *in vivo* evaluation of TEMPs for use in rotator cuff repair
- ★ [WK31014](#) New Test Method for Standard Method using Goat for *in vivo* Testing Articular Cartilage Repair or Regeneration

★ = Specific test method

ASTM – Current standards and work items **F04.45 and F04.46**

- **Subcommittee F04.45 on Adventitious Agents Safety**
- [F2383-11 Standard Guide for Assessment of Adventitious Agents in Tissue Engineered Medical Products \(TEMPs\)](#)
- [WK20564](#) New Guide for Adventitious agent safety in xenogeneic TEMPs
- **Subcommittee F04.46 on Cell Signaling**
- No Active Standards
- [WK17329](#) New Terminology for Terminology for Cell Signaling Related to Medical And Surgical Devices
- [WK17626](#) New Guide for Using Fluorescence Microscopy to Quantify the Spread Area of Fixed Cells
- [WK28948](#) New Practice for /Guide for Use of Fluorescent Materials for Tagging Cells
- [WK33434](#) New Guide for Performing Quantitative Fluorescence Intensity Measurements in Cell-based Assays with Epifluorescence Microscopy

ASTM Scaffolds Workshop

Title: Standards and Measurements for Tissue Engineering Scaffolds: What Do We Have & What Do We Need?

When & Where: May 21, 2013 (during ASTM Standards Week in Indianapolis)

Sponsoring Committees:

- F04.04: Tissue Engineered Medical Products
- F04.42: Biomaterials & Biomolecules for TEMPs

Organizing Committee:

- Carl Simon (NIST)
- Michael Yaszemski (Mayo Clinic)
- Anthony Ratcliffe (Synthasome)
- Paul Tomlins (European Standards Consultant)
- Reto Luginbuehl (RMS)
- John Tesk (Consultant)



Objective: The purpose of the workshop was to identify the highest priority items for future standards work for scaffolds for TEMPs

Target Audience: Those involved in developing scaffolds-based TEMPs including industry, government and academia

Output: Workshop conclusions will be summarized in a published paper

Link: <http://www.astm.org/F04Wrshhp0513.htm>

ASTM Scaffolds Workshop Agenda

Part 1: Introduction (Carl Simon, NIST)

Carl Simon (NIST)

Byron Hayes (Gore)

Reto Luginbuehl (Robert Mathys Foundation)

Part 2: Needs Revealed by Clinical Research Experience (Ryan Roeder, Notre Dame)

Michael Yaszemski (Mayo Clinic): bone & joint tissue engineering, guidance documents

Tony Ratcliff (Synthasome): articular cartilage, rotator cuff

David Kaplan (FDA)

Discussion: Gregory Brown (Park Nicollet Health Services)

Part 3: Hydrogels (Malcom Moos, FDA)

Michael Dornish (FMC BioPolymer)

Antonios Mikos (Rice Univ.)

Discussion: Michael Dornish (FMC Biopolymer)

Part 4: Solid Scaffolds (Stephanie Norris, Atex Technologies)

Barbara Boyan (Ga Tech)

Jed Johnson (Nanofiber Solutions)

Carlos Caicedo-Carvajal (3D-Biotek)

Kurt Sly (Exactech)

Discussion Leader: Barbara Boyan (Ga Tech)

Part 5: Natural Scaffolds & Characterization (Eugene Smit, Stellenbosch Nanofiber Company)

Michael Hiles (Cook Biotech): Decellularized ECM

Ted Wakatsuki (InVivoSciences): Collagen

Paul Tomlins (Consultant): Measuring porosity (millimeter to nanometer scale)

Joy Dunkers (NIST): Characterization

Carl Simon: Reference Materials

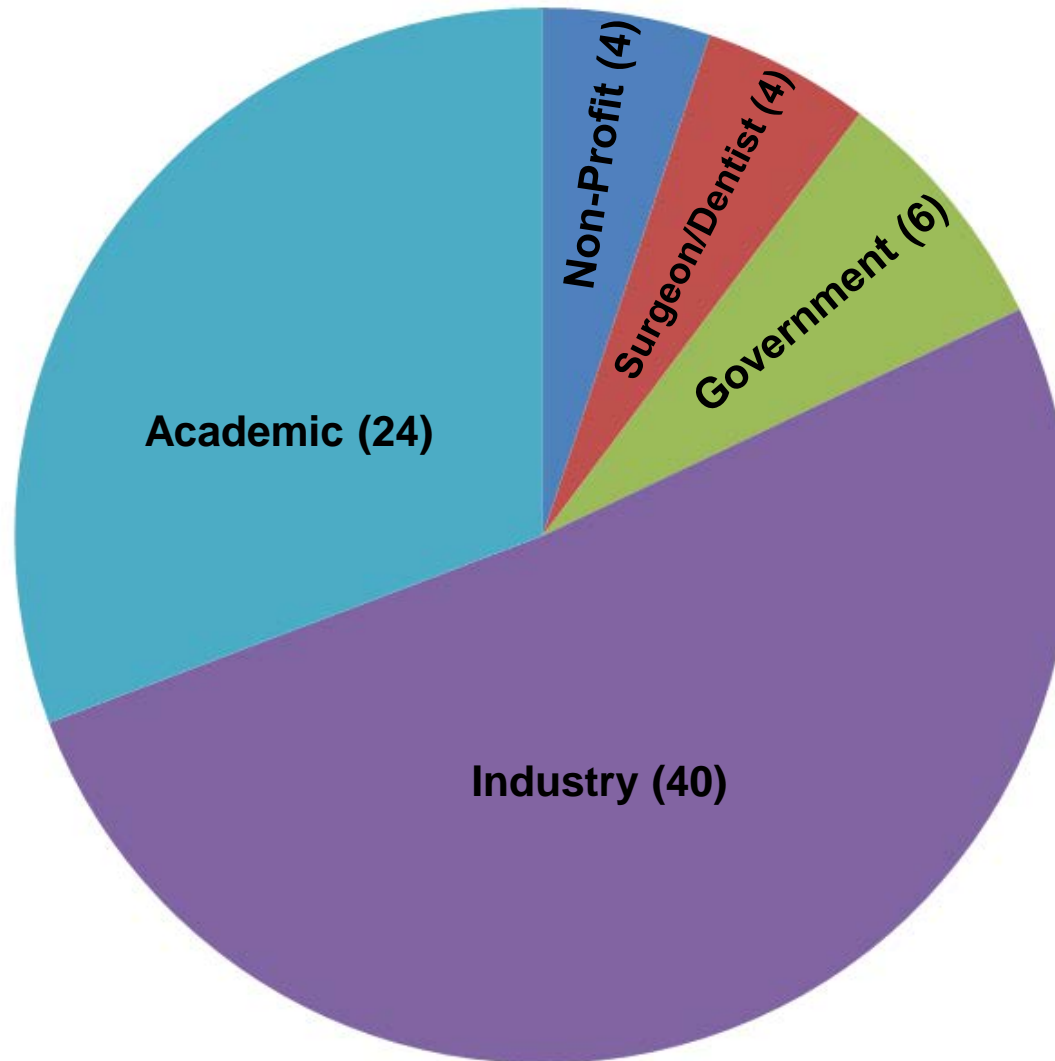
Discussion Leader: Jayesh Doshi (Espin Technologies)

Part 6: Conclusion

Final discussion (Carl Simon)

Closing remarks (Warren Haggard, F04.04 Chair)

ASTM Scaffolds Workshop Registrants (78)



Standards Needs Identified at the Scaffold Workshop

- **Need More Standard Test Methods:** We have many *guidance documents* for educational/advisory purposes, but few *standard test methods*
- **1st priority - Scaffold Structure:** Overwhelmingly, the most clearly identified need was standards for measuring scaffold structure
- **2nd priority - Biological Characterization:** Second was standards for biological characterization including *in vitro* testing, animal models & cell-material interactions
- **3rd priority - Mechanical Properties:** Third was standards for measuring mechanical properties of scaffolds
- **Other Highlighted Standards Needs:**
 - Standards for measuring scaffold degradation
 - Need reference materials to enable measurement comparisons between different labs (scaffold reference materials)
 - Standards for assessing clinical outcomes
 - Standards for measuring scaffold composition
 - Standards for reporting research results
 - Standards for assessing effect of sterilization on scaffold properties
 - Standards for assessing drug release from scaffolds

Identification of scaffold related standards needs

- Measurement of scaffold structure, mechanics and degradation
- Evaluation of scaffold toxicity, biocompatibility and cell/material interactions
- Assessment of *in vivo* scaffold performance in animals and in patients
- Measurement of scaffold composition
- Assessment of effect of sterilization
- Measurement of drug release

Resources

- www.astm.org
- Search under F04.41, F04.42, F04.43, F04.44, F04.45, F04.46.
- http://www.astm.org/toolkit/images/ASTM%20Information/Industry_Sector_Overviews/Medical_Overview.pdf
- ASTM Scaffolds workshop
 - <http://www.astm.org/F04Wrshhp0513.htm>

Speaker Contact Information

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